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28 JUNE 2002
HUESCHEN AND SAGE

G. J. SAGE
Dated: 28 JUNE 2002

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PF 83 PCT US *RESPONSE*

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Applicant : CHEVALET, et al.
Serial No. : 09/673,288
Filed : December 7, 2000
Title : Novel constructs for controlled expression of recombinant proteins in prokaryotic cells.
Art Unit : 1642
Examiner : Konstantina KATCHEVES, Esq.

Honorable Commissioner of Patents and Trademarks
Washington, D.C. 20231

SUPPLEMENTAL RESPONSE & AMENDMENT UNDER 37 CFR §§ 1.111 & 1.115

Sir:

Responsive to the Office Action dated May 23, 2001, and in further response to the Response to Amendment of May 30, 2002, the Applicants acknowledge the Examiner's comprehensive Office Action with appreciation. Claims 1-21 remain under consideration. The Examiner has objected to the Specification for a variety of reasons. Claims 1-9, 12-14, and 17 are rejected under 35 USC § 112, first paragraph.

With the instant action, the Examiner emphasizes the 35 USC § 112, first paragraph, rejection as drawn to the written description requirement of the section. The Examiner notes that "...the specification fails to disclose to one of skill in the art how to obtain the fragments embraced by the scope of the claims...". In response thereto, the Applicants note that relevant references are

disclosed in the Specification, which references describe the TnaA and TrpR sequences (see Deeley and Yanofsky, (1981), and Gunsalus and Yanofsky, (1980)). What is more, it is clearly stated in the description that the TnaA sequence is modified so as to result in the loss of tryptophanase activity. The biologically active fragments of the TrpR are defined in the description as fragments which keep their repressor activity. Thus, it is submitted that the Applicants have not only provided evidence that the basic sequences are known in the art, but also described the characteristics of the fragments of the methods claimed.

In addition, it is suggested that the "claims read on any nucleic acid". Clearly this is not the case. The description includes sequence definition, such as:

- the nucleic acid sequence which is capable of inactivating the gene...
- when said nucleic acid sequence (i.e. which is capable of inactivating the gene)...
- and integrating said sequence (i.e. which is capable of inactivating the gene)...
- sequence of a promoter...
- nucleic acid sequence encoding a molecule.

This description is incorporated into the claims as well. In the generic claim, the sequence is defined by its activity, namely, that it must be capable of inactivating the gene encoding a TnaA tryptophanase.

Thus, the Examiner will note that the Applicants have described the subject matter of the invention to the extent appropriate for one skilled in the art to practice the method of the invention.

* * * * *

Accordingly, entry of the present amendment, reconsideration of all grounds of objection and rejection, withdrawal thereof, and passage of this application to issue are all hereby respectfully solicited.

It should be apparent that the undersigned attorney has made an earnest effort to place this application into condition for immediate allowance. If he can be of assistance to the Examiner in the elimination of any possibly-outstanding insignificant impediment to an immediate allowance, the Examiner is respectfully invited to call him at his below-listed number for such purpose.

Allowance is solicited.

Respectfully submitted,
THE FIRM OF HUESCHEN AND SAGE

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